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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER

KIM, YOUNG J

ART UNIT

PAPER NUMBER

1637

DATE MAILED: 10/06/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/089,498	Applicant(s) LEE ET AL.	
	Examiner Young J. Kim	Art Unit 1637	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
 - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
 - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
 - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-35 is/are pending in the application.
 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-27, 29-31 and 33 is/are rejected.
- 7) ☒ Claim(s) 5, 13, 16, 28, 32, 34 and 35 is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 28 March 2002 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>6/14/2002</u> . | 6) <input type="checkbox"/> Other: ____. |

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DETAILED ACTION

Preliminary Remark

The Group and/or Art Unit location of your application in the PTO has been assigned to Art Unit 1637. All further correspondence regarding this application should be directed to Young J. Kim in Group Art Unit 1637.

Corrected Filing Receipt

Applicants' request for the issuance of corrected filing receipt, received on July 1, 2002, changing the spelling of the town of the first inventor from "Wiltshire" to --Wiltshire-- is noted. The corrected filing receipt is attached hereto.

Information Disclosure Statement

The Office acknowledges the IDS received on June 14, 2002. A signed copy of its corresponding PTO-1449 is attached hereto.

Drawings

The Drawings filed on March 28, 2002 are acceptable.

Specification

The specification, while containing the section of description of the drawings, does not have a proper header titled, "BRIEF DESCRIPTION OF THE DRAWINGS" as required by MPEP 608.01(a), requiring said description be, "preceded by a section heading in uppercase and without underlining or bold type." (MPEP 608.01(a)).

The use of the trademark TWEEN and TRITON has been noted in this application. It should be capitalized wherever it appears and be accompanied by the generic terminology.

Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner which might adversely affect their validity as trademarks.

Priority

Applicants' claim to foreign priority to application 9922971.8, filed on September 29, 1999, filed in United Kingdom, is acknowledged.

The specification is objected to by the Examiner because the Preliminary Amendment received on March 28, 2002, amends the specification, claiming the benefit of the filing date of the international application of which it is the national stage. A national application filed under 35 U.S.C. 371 may not claim benefit of the filing date of the international application of which it is the national stage since its filing date is the date of filing of that international application. Since the international application is not an earlier application (it has the same filing date as the national stage), a priority claim in the national stage to the international application is inappropriate. Accordingly, it is not necessary for the applicant to amend the first sentence of the specification to reference the international application for a national stage application filed under 35 U.S.C. 371 (See also MPEP 1893.03(b)).

Applicants are advised that only the priority benefit claims under 35 U.S.C. 119(e) and 120 require the first line of the specification to make reference to the earlier filed application(s). Therefore, the priority claims made under 119(a)-(d), *i.e.*, foreign priority, need not be made in the specification so long as it is claimed in the Application Data Sheet or the Oath/Declaration.

Sequence Rules

This application contains sequence disclosures that are encompassed by the definition for nucleotide and/or amino acid sequences set for in 37 CFR 1.82(a)(1) and (a)(2). For example, page 15 of the specification contains nucleotide sequences which are more than ten contiguous nucleotides in length without their SEQ ID identifiers. Therefore, this application fails to comply with the requirement of 37 CFR 1.821 through 1.825 for the reason(s) set forth on the attached Notice To Comply With Requirements For Patent Applications Containing Nucleotides Sequences And/Or Amino Acid Sequence Disclosures. Since the non-compliance is immaterial to the claim examination, the application has been acted on **with Supervisory approval**.

A Paper Copy of the Sequence Listing, a computer readable format (CRF), and a statement under 37 CFR 1.821(f), fully compliant with the above stated rules, are **required** for a response to be **fully responsive**.

Claim Objections

Claim 5 is objected to because of the following informalities: claim 5 uses the symbol, “@” to mean the word, “at.” For the sake of clarity and preclude confusion, Applicants are advised to fully write out the word instead of using its short-term represented by said symbol. Appropriate correction is required.

Claim 13 recites the term, “heat sealed.” From the context of the claim, it appears that the term should read, “heat-sealed” to avoid confusion.

Claim 16 recites the phrase, “[t]he method according to claim 1 ***which further comprises a spacing layer having holes and channels to define reagent wells...***” Claim 16 is objected to because the limitation does not further define the method step, but rather the disposable unit of

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claim 1. Amending the claim to recite, “[t]he method according to claim 1, *wherein said disposable unit* further comprises a spacing layer...” would obviate this objection.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-27 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 and its dependent claims 2-26 recite the limitation "the reaction mixture." There is insufficient antecedent basis for this limitation in the claim and therefore, causes the below confusion.

Claim 1, sub-step (b) recites that the method employs, “primers, nucleotides and enzymes,” and “a buffer system,” followed by the phrase, “the reaction mixture.” The antecedent basis of “the reaction mixture,” therefore, had been assumed to include, primers, nucleotides, enzymes, and a buffer system.” However, in a subsequent phrase, “the reaction mixture,” is recited as comprising at least one of buffer system, a detergent, and/or blocking agent, resulting in the confusion of what elements are included by the use of the antecedent term, “the reaction mixture.”

Claim 1 is confusing because the claim interchangeably recites the term, “well” and “reagent well.” Therefore, it is unclear whether the two terms are the same, or the disposable

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unit has a well as well as reagent wells. This confusion is aggravated by claims 18 and 19, wherein the claims also use the term, “reagent well” and “the wells,” respectively.

Claim 2 is indefinite because the claim does not further limit its parent claim. Specifically, claim 2 recites the phrase, “the method of according to claim 1, wherein the p.H. of the buffer system is above 8.3.” The p.H. of the buffer system, however, has already been defined as above 8.3 in the previous claim. It appears that the phrase should recite, “the method according to claim 1, wherein the reaction mixture comprises the buffer system, wherein the p.H. of said buffer system is above 8.3” to further limit the reaction mixture.

Claim 5 is dependent on itself, thus failing to establish a proper antecedent basis for terms used in the claim. For the purpose of prosecution, the claim is interpreted as being dependent on claim 4.

Claim 7 is indefinite for the use of Trademarks, TweenTM and TritonTM. The use of trademarks renders the claim indefinite because the formula or characteristics of the product may change from time to time and yet it may continue to be sold under the same trademark (MPEP 608.01(v)). Since the specification does not contain a definition of the above elements, the elements are defined only by their trademark name which could be changed from time to time.

Claims 10-12 recite the limitation “the thermally conducting *metal layer*.” There is insufficient antecedent basis for this limitation in the claim. It appears that the claims should be dependent on claim 9. For the purpose of prosecution, this interpretation has been made.

Claim 20 is dependent on claim 15, which does not establish a proper antecedent basis for terms used in the claim. For the purpose of prosecution, the claim is interpreted as being dependent on claim 19.

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Claim 22 is improperly multiple dependent because the claims initially depends on claim 1, as recited by the phrase, "The method according to claim 1," but later recites that an apparatus comprises a conveyor means, "according to any one of the preceding claims," resulting in double dependencies.

Claim 24 is indefinite for the recitation of the phrase, "the heating block," because claim 24 depends from claim 22, which recites that the apparatus has at least two heating blocks. Therefore, the use of the phrase, "the heating block," renders claim 24 indefinite in which of the at least two heating blocks, the phrase is describing. Amending the claim to recite the phrase, "the heating blocks," would overcome this rejection.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1, 2, 4, 6, 7, 25, and 26 are rejected under 35 U.S.C. 102(b) as being anticipated by Innis et al. (U.S. Patent No. 5,075,216, issued December 24, 1991).

Innis et al. disclose a method of amplifying a target nucleic acid molecule, said method involving the steps of: a) providing a sample comprising a target nucleic acid; b) providing primers, nucleotides, and enzymes; c) a buffer system which allows amplification, wherein said

buffer system comprises TrisHCl, the concentration of which is in the range of 10mM (column 7, line 54) to 50mM (column 14, lines 31-33) at p.H. of 8.0 to 8.5 (column 7, line 55; column 14, line 33), a detergent Tween in the amount of 0.05% (column 7, lines 54-55).

Therefore, Innis et al. anticipate the invention as claimed.

Claims 1, 4, and 8 are rejected under 35 U.S.C. 102(b) as being anticipated by Hartley (U.S. Patent No. 5,043,272, issued August 27, 1991).

Hartley discloses a method of amplifying a target nucleic acid molecule, said method comprising the steps of: a) providing a sample comprising a target nucleic acid; b) providing primers, nucleotides, and enzymes; c) a buffer system which allows amplification, wherein said buffer system comprises, 50mM Tris HCl, detergent, TweenTM, and bovine serum albumin (or BSA) (column 2, line 62-23; column 4, lines 27-31; column 10, lines 1-5; column 12, line 9).

Therefore, Hartley anticipates the invention as claimed.

Claims 29-31 and 33 are rejected under 35 U.S.C. 102(e) as being anticipated by Foote (U.S. Patent No. 5,944,971, issued August 31, 1999, priority September 29, 1995; cited in IDS received June 14, 2002).

Foote discloses a disposable unit comprising a thermally conducting layer – glass, silicon, ceramics (Figure 1; column 5, lines 56-60) – and a facing layer (or cover plate in column 5, lines 50-64) having a plurality of reagent wells defined therebetween (or parallel channels in Figure 1, items 22 and 24; column 5, lines 53-55), wherein all wells are fed by a common channel of manifold connecting channel (item 20 of Figure 1; column 6, lines 61-63), anticipating claim 29.

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The wells of the disposable unit of Foote is disclosed as having probe/primer oligonucleotides immobilized therein (column 7, lines 21-3; Figure 3), thereby anticipating claims 30 and 31.

Foote discloses a method of filling their disposable unit with reagents or wash solutions (therefore liquid), wherein micropipetting procedure is used (column 7, lines 12-20). Micropipetting applies air pressure to force the reagents out of the pipet into the disposable unit, rendering claim 33 anticipated.

With regard to the intended use limitation of claim 30, reciting the phrase, "for conducting thermal cycling reaction," said phrase is not given patentable weight as all of the elements of the product claim is taught by the artisan.

Therefore, Foote anticipates the invention as claimed.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 3 and 8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Innis et al. (U.S. Patent No. 5,075,216, issued December 24, 1991) in view of Hartley (U.S. Patent No. 5,043,272, issued August 27, 1991) and Cheng (U.S. Patent No. 5,512,462, issued April 30, 1996).

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Innis et al. disclose a method of amplifying a target nucleic acid molecule, said method involving the steps of: a) providing a sample comprising a target nucleic acid; b) providing primers, nucleotides, and enzymes; c) a buffer system which allows amplification, wherein said buffer system comprises TrisHCl, the concentration of which is in the range of 10mM (column 7, line 54) to 50mM (column 14, lines 31-33) at p.H. of 8.0 to 8.5 (column 7, line 55; column 14, line 33), a detergent Tween in the amount of 0.05% (column 7, lines 54-55).

Innis et al. do not disclose the use of blocking agent, such as BSA or bovine serum albumin, nor the pH of an amplification buffer system in the range of 8.7-9.0, or specifically at 8.8.

Hartley discloses a method of amplifying a target nucleic acid molecule, said method comprising the steps of: a) providing a sample comprising a target nucleic acid; b) providing primers, nucleotides, and enzymes; c) a buffer system which allows amplification, wherein said buffer system comprises, 50mM Tris HCl, detergent, TweenTM, and bovine serum albumin (or BSA) (column 2, line 62-23; column 4, lines 27-31; column 10, lines 1-5; column 12, line 9).

Cheng discloses a method of amplifying a target nucleic acid, wherein the desired p.H. level of the amplification buffer is in the range of 8.5 to 8.7 at 25°C (column 10, lines 13-16).

It would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to combine the teachings of Innis et al. with that of Hartley to arrive at the invention as claimed.

While Innis et al. do not explicitly disclose the use of a blocking agent, as demonstrated by Hartley, the use of BSA in an amplification reaction has long been established in the art for

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the advantage of increasing the yield of the amplification product. This well-known fact is evidenced by Cheng, wherein the artisan states:

“Increased yield of amplified product may be obtained by addition of up to 500µg/ml of nonacetylated BSA to the amplification reaction.” (column 19, lines 40-43).

Therefore, one of ordinary skill in the art would have been readily motivated to combine the teachings of Hartley for the well-known advantage of using BSA in an amplification, in order to increase product yield, as evidenced by Cheng.

With regard to the motivation to modify the p.H. condition of Innis et al to the range of 8.7-9.0, such motivation is provided by Hartley, wherein the artisan states:

“[m]ethods are known to render double-stranded nucleic acids into single-stranded, or partially single-stranded, forms, such as heating, preferably by heating to about 90°-100°C for about 1 to 10 minutes, *or by alkali treatment, such as a pH greater than 12.*” (column 3, lines 42-46).

While Hartley states that a “pH greater than 12” for rendering single-stranded, a double-stranded nucleic acid, such should be understood as a non-limiting example which does not limit the knowledge of an ordinarily skilled artisan. This is evident as Hartley also discloses, in a non-limiting example, “raising the pH of the reaction buffer to 7.1,” would enhance the amplification reaction (column 11, lines 55-61). This fact is further substantiated by Cheng who teaches an amplification buffer having the p.H. range of 8.5 to 8.7 at 25°C (column 10, lines 13-16).

Therefore, one of ordinary skill in the art would have been motivated to adjust the p.H. of the amplification buffer to arrive at the claimed invention with a clear reasonable expectation of success.

Claim 5 is rejected under 35 U.S.C. 103(a) as being unpatentable over Innis et al. (U.S. Patent No. 5,075,216, issued December 24, 1991) in view of Hartley (U.S. Patent No. 5,043,272, issued August 27, 1991) and Cheng (U.S. Patent No. 5,512,462, issued April 30, 1996) as applied to claims 3 and 8 above, and further in view of Burckhardt (U.S. Patent No. 5,501,963, issued March 26, 1996).

The teachings of Innis et al., Hartley, and Cheng have already been discussed above.

The above artisans do not explicitly teach an amplification buffer having the p.H. of 8.8.

Burckhardt discloses an amplification buffer comprising the 50mM buffer of p.H. of 8.8 at 25°C (column 10, line 20).

It would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to modify the teachings of Innis et al., Hartely and Cheng with the teachings of Burckhardt for the following reasons.

The motivation to modify the p.H. condition of Innis et al to 8.8, is provided by Hartley, wherein the artisan states:

“[m]ethods are known to render double-stranded nucleic acids into single-stranded, or partially single-stranded, forms, such as heating, preferably by heating to about 90°-100°C for about 1 to 10 minutes, ***or by alkali treatment, such as a pH greater than 12.***” (column 3, lines 42-46).

While Hartley states that a “pH greater than 12” for rendering single-stranded, a double-stranded nucleic acid, such should be understood as a non-limiting example which does not limit the knowledge of an ordinarily skilled artisan. This is evident as Hartley also discloses, in a non-limiting example, “raising the pH of the reaction buffer to 7.1,” would enhance the amplification

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reaction (column 11, lines 55-61). This fact is further substantiated by Cheng who teaches an amplification buffer having the p.H. range of 8.5 to 8.7 at 25°C (column 10, lines 13-16) as well as Burckhardt who teaches an amplification buffer having the p.H. of 8.8 at 25°C (column 10, line 20).

Therefore, one of ordinary skill in the art would have been motivated to adjust the p.H. of the amplification buffer to arrive at the claimed invention with a clear reasonable expectation of success.

Claim 13-16, 18, and 27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Innis et al. (U.S. Patent No. 5,075,216, issued December 24, 1991) in view of Kris et al. (U.S. Patent No. 6,238,869 B1, issued May 29, 2001, filed June 21, 1999).

Innis et al. disclose a method of amplifying a target nucleic acid molecule, said method involving the steps of: a) providing a sample comprising a target nucleic acid; b) providing primers, nucleotides, and enzymes; c) a buffer system which allows amplification, wherein said buffer system comprises TrisHCl, the concentration of which is in the range of 10mM (column 7, line 54) to 50mM (column 14, lines 31-33) at p.H. of 8.0 to 8.5 (column 7, line 55; column 14, line 33), a detergent Tween in the amount of 0.05% (column 7, lines 54-55).

Innis et al. do not explicitly teach that the reagents could be packaged into a kit further comprising at least one disposable unit having a plurality of wells.

While the use of microtiter (in the form of 96 wells) plates is well-known in the art of amplification, and Innis et al. do not explicitly state the use of such plates, Kris et al., state that 96, 384, 1536-well microtiter plates are well-known and commercially available (column 13,

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lines 26-30). While the microtiter plate of Kris et al. is not explicitly disclosed as thermally conducting, the make up of the plate would necessarily conduct heat for the thermocycling to occur. The limitation, "thermally conducting layer," based on a broadest reasonable interpretation, is determined to be a layer which passes heat. Whether the microtiter of Kris et al. is a good thermal conductor or not is not considered in this broad interpretation so long as the heat is passed through.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to package the reagents employed in the method of Innis et al. with the microtiter plate of Kris et al. in view of the conventionality of kits in the analytical arts for the advantages of convenience, cost-effectiveness, matched and/or preweighed components, etc.

Therefore, the invention as claimed is obvious over the cited references.

Claims 19 and 20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Innis et al. (U.S. Patent No. 5,075,216, issued December 24, 1991) in view of Little et al. (U.S. Patent No. 6,077,669, issued June 20, 2000, filed November 7, 1997).

Innis et al. disclose a method of amplifying a target nucleic acid molecule, said method involving the steps of: a) providing a sample comprising a target nucleic acid; b) providing primers, nucleotides, and enzymes; c) a buffer system which allows amplification, wherein said buffer system comprises TrisHCl, the concentration of which is in the range of 10mM (column 7, line 54) to 50mM (column 14, lines 31-33) at p.H. of 8.0 to 8.5 (column 7, line 55; column 14, line 33), a detergent Tween in the amount of 0.05% (column 7, lines 54-55).

Innis et al. do not explicitly teach that the reagents could be predosed in dried forms in at least one disposable unit having a plurality of wells.

Little et al. disclose a well-known method of providing reagents in a dried form in a disposable device (column 2, lines 30-34).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to provide the reagents of Innis et al. in their dried forms in the wells of a disposable device in order to provide devices comprising matched and preweighed reagents, for the obvious advantage of reducing contamination, and eliminating the time consuming steps of adding appropriate amounts of reagents for reactions to occur.

Therefore, the invention as claimed is obvious over the cited references.

Claims 22-24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Innis et al. (U.S. Patent No. 5,075,216, issued December 24, 1991) in view of Danssaert et al. (U.S. Patent No. 5,525,300, issued June 11, 1996).

Innis et al. disclose a method of amplifying a target nucleic acid molecule, said method involving the steps of: a) providing a sample comprising a target nucleic acid; b) providing primers, nucleotides, and enzymes; c) a buffer system which allows amplification, wherein said buffer system comprises TrisHCl, the concentration of which is in the range of 10mM (column 7, line 54) to 50mM (column 14, lines 31-33) at p.H. of 8.0 to 8.5 (column 7, line 55; column 14, line 33), a detergent Tween in the amount of 0.05% (column 7, lines 54-55).

Innis et al. do not teach the disposable unit being placed in an apparatus comprising at least two heating blocks.

Danssaert et al. disclose an apparatus comprising multiple heating blocks, said apparatus comprising: a) a plurality of reaction blocks (Figure 1, components 3, 17, 18, and 19), wherein at least one of the blocks is a heat reaction block and at least one of the blocks is a cold reaction block (Figure 3), wherein a reaction vessel (Figure 1, component 20) has a plurality of openings formed therein; b) a robotic arm which transfers the reaction vessels from one hot reaction block to one cold reaction block (Figure 1; column 1, lines 29-35; column 4, lines 35-42; column 5, lines 42-45); and c) a controller having a user interface for inputting temperature and sampling interval, the controller in communication with the blocks and robotic device (column 5, lines 25-42). The apparatus of Danssaert et al. conducts PCR (polymerase chain reaction) which is considered to be non-isothermal reaction (column 7). With regard to the apparatus of Danssaert et al., as well as most of the thermocycler, display the cycle times and their corresponding temperature at said cycle (Figure 1, component 16).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to combine the teachings of Innis et al. with the apparatus of Danssaert et al. for the advantage of determining the optimal temperatures required in a PCR reaction (column 3, lines 5-8, Danssaert et al.).

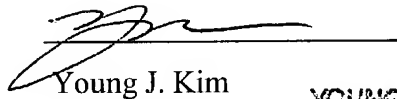
Therefore, the invention as claimed is obvious over the cited references.

Inquiries

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Young J. Kim whose telephone number is (571) 272-0785. The Examiner can normally be reached from 8:30 a.m. to 6:00 p.m. Monday through Thursday. If attempts to reach the Examiner by telephone are unsuccessful, the Primary Examiner in charge of the prosecution, Dr. Kenneth Horlick, can be reached at (571) 272-0784. If the attempts to

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reach the above Examiners are unsuccessful, the Examiner's supervisor, Gary Benzion, can be reached at (571) 272-0782. Papers related to this application may be submitted to Art Unit 1637 by facsimile transmission. The faxing of such papers must conform with the notice published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December 28, 1993) (see 37 CFR 1.6(d)). NOTE: If applicant does submit a paper by FAX, the original copy should be retained by applicant or applicant's representative. NO DUPLICATE COPIES SHOULD BE SUBMITTED, so as to avoid the processing of duplicate papers in the Office. All official documents must be sent to the Official Tech Center Fax number: (703) 872-9306. For Unofficial documents, faxes can be sent directly to the Examiner at (571) 273-0785. Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (571) 272-1600.



Young J. Kim
Patent Examiner
Art Unit 1637
9/22/04

YOUNG J. KIM
PATENT EXAMINER

yjk